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EXAMINER

LEVKOVICH, NATALIA A

ART UNIT	PAPER NUMBER
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1797

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/089,136	Applicant(s) HEIMBERG ET AL.	
	Examiner NATALIA LEVKOVICH	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 December 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19,21-23,25,27,35,37,41,43,49 and 53-56 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19,21-23,25,27,35,37,41,43,49 and 53-56 is/are rejected.
- 7) ☒ Claim(s) 21-22 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/26/2008</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/17/2008 has been entered.

Drawings

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims, as well as any structural detail that is essential for a proper understanding of the disclosed invention. Therefore, the gaps between the segments, must be clearly shown and referenced, or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be

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canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance

Claim Objections

3. Claims 21 and 22 are objected to because they are substantial duplicates of one another. Note that when two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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5. Claims 19, 21-23, 25, 27, 35, 37, 41, 43, 49 and 53-56 are rejected under 35 U.S.C. 112, second paragraph, as being unclear for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The amended claim 19 recites a control unit for “actuating the system, wherein the devices are actuated independently of one another to set and maintain different temperatures in two adjacent segments”. It is unclear whether or not this means that the heating and cooling devices must be connected to the control unit which, in turn, must be connected to temperature sensors, for providing a feedback. It is also unclear whether or not any setting means allowing a user to set desired temperature(s), are intended (see also claim 49 regarding the predetermined temperature difference). The claim further recites the system providing “different temperatures to the segments during a temperature cycle to optimize the parameters for PCR”. It is not clear how the “different temperatures” are related to the parameters to be optimized. Additionally, it is unclear if any means for measuring a result variable needed as a criterion to evaluate whether or not the parameters for PCR were optimized, are intended. Referring to the recitation of the heating and cooling devices being “aligned with and dedicated to only one segment”, it remains unclear whether or not this means that each such device must be thermally connected to a respective segment in the ‘one-to-one’ fashion, or that all the devices must be connected to the very same segment in the ‘one-to-many’ manner.

In claim 37, the ‘recesses’ lack antecedency.

Regarding claim 41, it is not clear how the functionality recited in the claim can

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be implemented without the temperature sensors being connected to the control unit.

Claim 56 recites the “system of claim 19, further comprising a control unit for actuating the two or more devices, wherein each of the two or more devices is individually actuated”. It is not clear whether or not Applicant is trying to claim a second control unit connected to the heating and cooling devices of claim 19.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 19, 21-23, 25, 27, 35, 37, 41, 43, 49 and 53-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gordon et al. (US 5601141) in view of Potter et al. (US 5819842).

In reference to claims 19, 21-22, 35, 37, 41 and 56, Gordon discloses a modular thermal cyclor that carries samples through one or more predetermined temperature

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profiles and comprises a base with an array of modules ['segments'] mounted on the base. The modules are "substantially isolated from one another, thermally and functionally", each module including a temperature sensor "adjacent the samples, an electrical resistance heating element, and a circulating fluid heat exchanger for step cooling...The modules are preferably formed in three layers--a sample plate ['thin-walled reaction vessel holders'- see element 14a of Figure 4], a heater plate, and a cooling plate ['devices for heating and cooling', see elements 14 b-c of Figure 4] adjacent to a manifold... The sample plate is preferably replaceably secured at the upper surface of the module on the heating plate... The sample plate is adapted to receive a *standard micro-titration plate*, or other labware, in a close, heat-transmitting engagement. The heater plate and cooling plate may be formed integrally"- (Abstract; Col.1, line 5; Col.2, lines 10-40). Gordon also teaches that the thermal cycler includes a controller which "regulates the electrical current and cooling fluid flows to each module in response to a signal from a temperature sensing element associated with each module"(Col.2, lines 15-20; Col.4, line 45; Col.5, line 55). Thus, the multiple modules ['segments'] of Gordon are configured to control sample temperatures in multiple standard micro-titer plates independently.

Gordon, however, does not explicitly describe an embodiment with the segments of the micro titer plate receiving element being sized to receive a single standard micro-titer plate for independently controlling corresponding portions of the micro-titer plate. On the other hand, Gordon does teach that "In biological and chemical testing and experiments it is often necessary to repeatedly cycle samples of a biological specimen

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or chemical solution through a series of different temperatures where they are maintained at different set temperatures for predetermined periods of time Modern biological testing often uses micro-titration plates. A standard such plate is a plastic sheet with 96 depressions, each adapted to hold one of the samples to be processed" (Col.1, lines 9-19). Gordon also teaches that cycling the samples in groups, independently of one another, can be organized both "as a single module or zone or as groups of modules or zones"(see Col.2, lines 55-59).

Potter et al. disclose a device for independent temperature control of multiple samples disposed in different portions of a single micro-titer plate (see Abstract). The device comprises, as shown in Figures 1-3, a standard micro-titer plate 10 with wells 13, the temperature within each well being independently controlled by physically distinct segments 21 of sample vessel receiving structure 20, the segments being aligned with respective physically distinct temperature controlling elements 22. Potter also discloses Peltier thermoelectric devices (very well known in the art as devices for providing both heating and / or cooling) as possible embodiments for the elements 22 (see Col.2, line 43). It would have been within the ordinary skill of an artisan at the time the invention was made to have modified the apparatus of Gordon such as to configure the independently controlled modules / sections for individual and independent heating / cooling of separate portions of a single standard micro-titer plate, in order to allow separate temperature control for some of the samples of the micro-titer plate (particularly when a single module thermal cycler is employed as an option, as taught by

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Gordon), which would also broaden the scope of applicability of the apparatus, as well as would further enhance its commercial / marketing value.

Referring to claims 21-22, the base can be “changed easily to accommodate different sample holders adapted to different labware, or to hold samples directly” (Col.4, line 20). In particular, Figure 4 shows micro-titration plate P disposed over plate 14a [‘reaction vessel receiving element’] having a base forming one piece with a plurality of wells [‘tubular, thin-walled reaction vessel holders’].

With respect to claims 23 and 25, Gordon teaches that “the modules are spaced laterally, from one another which in combination with forming the base of the insulator, provides a good degree of thermal isolation of each module” (Col.3, lines 40-45). It would have been also within the ordinary skill of an artisan at the time the invention was made to have modified the thermal conductivity of the gaps (depending on particular goals of thermo-cycling) by filling them with materials having different thermal conductivity characteristics (including thermal insulators), in order to provide flexible and precise temperature control in the modified apparatus of Gordon.

Regarding claim 27, Gordon refers to the use of Peltier elements for heating or cooling as being well known in the art in column 1, lines 30-35.

Regarding claim 43, Figure 6 shows channel temperature equalization element 46 filled with a heat dissipating fluid.

With respect to claims 49, and 53-55 which recite limitations to the process of using the device, these limitations are not attributed patentable weight in a claim to an apparatus. Additionally, it appears that the apparatus of Gordon et al. is capable of

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operating in the recited manner. Gordon modified by Potter would have suggested a segmented receiving element capable of being independently heated / cooled, that is, a structure capable of maintaining a predetermined temperature difference between adjacent segments and , therefore, capable of being used for optimizing temperature related process parameters.

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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10. Claims 19, 21-23, 25, 27, 35, 37, 41, 43, 49 and 53-56 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-2 of co-pending application 11/470463, claims 1-2 of co-pending application 11/850345, claim 18 of co-pending application 11/450442, claim 18 of co-pending application 11/651986, and claim 26 of co-pending application 11/651985. Although the conflicting claims are not identical, they are not patentably distinct from each other because all the elements of the above listed claims of the co-pending applications are fully encompassed by the instant claims. See the appropriate paragraphs of the 06/12/2008 Office Action.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

11. Applicant's arguments filed 11/26/2008 have been fully considered but they are not persuasive, or moot in view of new grounds of rejection.

Applicant argues that "the purpose of Gordon et al. is to "provide a cyclor..., which can be adapted to process a variety of sample holders", each with their own microtiter plate" and that "to provide a single standard microtiter plate spanning an entirety of the plural modules of Gordon et al. is expressly against the disclosure thereof". Examiner disagrees. As was shown above, Gordon does teach that cycling the samples in groups, independently of one another, can be organized both "as a single module or zone or as groups of modules or zones"(see Col.2, lines 55-59). Examiner maintains that Gordon

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modified by Potter would have suggested a segmented receiving element sized to receive a micro-titer plate and capable of providing independent heating / cooling for the portions of the plate supported by different segments.

Applicant argues that “Potter et al., while disclosing heating and cooling elements, fails to disclose a physically distinct device for heating and cooling the reaction vessel receiving element, the device aligned with and dedicated to only one segment of a reaction vessel receiving element. Instead, the heater element 22 of Potter et al. is embedded in a matrix 24 which is in turn seated on a cooling arrangement 25/26/27, which cooling arrangement clearly spans the entire unit and thus all heater elements 22 in FIG. 2 thereof. Therefore, Potter et al. fail to teach or suggest a physically distinct device for heating and cooling the reaction vessel receiving element, wherein each device is aligned with and dedicated to only one segment”.

Examiner would like to remind that Potter was relied upon to support the concept of modular temperature control for portions of a single plate (which Potter does teach) and that the “physically distinct device for heating and cooling the reaction vessel receiving element, wherein each device is aligned with and dedicated to only one segment” is clearly disclosed in Gordon (see the references to elements 14 a [‘physically distinct holder’]; b [‘physically distinct heating device’];; c [‘physically distinct cooling device’] in the art rejection above).

Conclusion

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12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalia Levkovich whose telephone number is 571-272-2462.

The examiner can normally be reached on Mon-Fri, 2 p.m.-10 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Jill Warden/
Supervisory Patent Examiner, Art Unit 1797